

OSU ceded/deferred oversight of my study to an external IRB – How do I send in updated documents and approval notices?

1. Log in to iRIS
2. Click on “Start a Study Submission Form” in the “Featured Study Operations” menu.

The screenshot shows the iRIS TEST SITE dashboard. At the top, there is a navigation bar with the iRIS logo, user information, and a 'Log out' button. Below the navigation bar, there are two main sections: 'Featured Study Operations' and 'Tasks'. The 'Featured Study Operations' section contains a list of buttons: 'Create a New Study', 'View My Studies', 'Start a Study Submission Form' (highlighted with a red box), 'Track Approvals', and 'Incomplete Forms' (with a red '1' indicator). The 'Tasks' section contains two buttons: 'View All Tasks' (with a red '40' indicator) and 'View Study Tasks' (with a red '39' indicator). Below these sections is a 'Study Assistant' section with a 'Find a Study' button.

3. Click on the “Forms” icon under “Actions” on the row of the applicable study

The screenshot shows the 'All Studies' table in the iRIS system. The table has columns for 'Click to open', 'Study Status', 'Review Board', 'RB Number', 'RB Expiration', 'Study Title', 'Principal Investigator', and 'Actions'. The 'Study Status' column has four categories: 'Deferred' (green), 'Approved' (green), 'Pending - Submitted for Initial Review' (orange), and 'Returned for Corrections' (red). The 'Actions' column contains icons for 'History', 'Items', 'Forms', 'Hide', 'Copy', and 'Delete'. The 'Forms' icon in the first row is highlighted with a red box.

Click to open	Study Status	Review Board	RB Number	RB Expiration	Study Title	Principal Investigator	Actions
	Deferred	IRB	IRB-2019-0116	10/07/2024	Test Application 06/19/2019---	Andrews, Tiffany	
	Approved	IRB	IRB-2019-0123	06/24/2020	Testing ARC and new build	Coleman, Jillian M	
	Pending - Submitted for Initial Review	IRB	IRB-2019-0061		Table test	Coleman, Jillian M	
	Returned for Corrections	IRB	IRB-2019-0121	12/02/2019	Test - OSU Will Defer	Andrews, Tiffany	

4. Click on the “Start a new submission” icon next to the Deferral Update Form.

The screenshot shows a web application interface with a sidebar on the left and a main content area. The sidebar has tabs for 'All Studies', 'Recently Used', and 'Study Status'. The main content area is titled 'Submission Form List' and contains a table with columns for 'Version List', 'Start a new Submission', and 'Edit Incomplete Submissions'. The 'Deferral Update Form' row has a red box around its 'Start a new Submission' icon. To the right of the table is a search bar and an 'Actions' menu with options like 'History', 'Items', 'Forms', 'Hide', 'Copy', and 'Delete'.

5. When completing the Deferral Update form, if you are adding study team members, make sure to add them in section “A) Additional Investigators”, as section B is only for Non-research Support Staff (individuals who will not have access to participants, data, or specimens)

The screenshot shows a form titled 'Section view of the Form' and 'Entire view of the Form'. The form is for 'Oregon State University Human Research Protection Program'. It includes a 'Name of Principal Investigator' field with the name 'Tiffany Andrews'. Below this is a section titled '1.4 Submission details:' with a dropdown menu to describe the submission type. A question asks 'Did the submission to the external IRB include adding or removing OSU study team members?' with radio buttons for 'Yes' (selected) and 'No'. There are three sections for adding personnel: 'If applicable, please add the new Principal Investigator for the Study:', 'If applicable, please select the new Research Staff personnel:', and 'If applicable, please add any new Study Contact:'. The 'A) Additional Investigators' row in the second section is highlighted with a red box. Each section has an 'Add' button. At the bottom, there is a note: 'The Project Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).'

6. The application is the initial submission, which also acts as the protocol for the project and outlines the study. During revisions, the application will only need to be revised if the information in the application/protocol has been impacted. The “click here to attach the application” button is used to create a new version of the application. If revisions are needed, click the “click here to attach the application” button, then click “Add Revision”. You can now edit your application. When you are done editing, go to the last section of the application, then click ‘save and continue to next section’ (this will take you back to the revision form).

1.5 If the external submission impacts the OSU application, revise the application to reflect the changes:

 Click here to attach the application.

No Application has been associated with this submission.

Attaching Study Application

Select the application that you would like to attach and then click Save Attachment Save Attachment

Select	Show Rev.	Edit/View	Form Name	Approved	Create a Revised Application
Already Submitted			HRPP and IRB Application and Protocol Form (Version 1.6)	Yes	 Add Revision

7. If you are revising/replacing current versions of the external IRB approved documents, click on ‘Select or Revise Existing’, then choose to create a revision for the document you wish to revise/replace. The version number will automatically populate. Check the document out (will download to your device), make edits and save to your computer (if applicable). If you are simply uploading a new version, you can skip editing and saving the document and click on complete checkout, check in the new document, save document.

1.6 Please attach any documents that were approved by the IRB of record, along with the approval documentation:

 Select or Revise Existing

 Add a New Document

 Add Multiple Documents

Detach	Version	Title	Category	Expiration Date	D
No Document(s) have been attached to this form.					

Select Existing or Create Revised Study Document X

Select Category: --none-- Title:

Version #: Search level: Top All

Version Date: between Expiration Date: between

Document Outcome: --none--

5 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Title	Expiration Date	Document Outcome	Checked Out By	View Document	Create Revision
				1.1	06/19/2019	Questionsfortesting					
						Interview Guide	06/18/2024	Approved		38.80 KB	
				1.2	06/19/2019	Recruitmentfortesting					
						Recruitment Document				11.73 KB	
				1.0	10/08/2019	External IRB approval					
						External IRB Documents				11.62 KB	
				1.0	10/08/2019	Approval Recruitment from External IRB					
						Recruitment Document				11.73 KB	
				1.0	10/08/2019	External Updated Questionnaire					
						Interview Guide				12.70 KB	

Study Document Revision: X

*Document Title:

Version Number: .1

Version Date:

Category:

Description:

Check-out the Document to your workstation for editing:

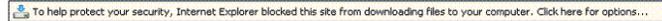
Comments:

Download the Study Document

INSTRUCTIONS

Step 1:

If your browser blocks pop - ups, then after a few moments a bar similar to the one shown below may appear in your browser.



Simply click on the bar and a small drop down list will appear. Click **Download File** from the list of options.



Step 2:

In a few moments, your browser will prompt you to either **Open** or **Save** the file (see example below).

Note: this is not the actual File Download box, it is only a picture. In order to **Check - out** the document and edit it, you will need to **Save** it to your workstation.



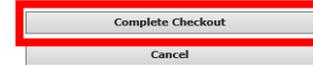
To do so, click **Save**. This will open up a window similar to the one shown below that allows you to choose where in your workstation you would like to save the document.

Once you've selected where you will save the document, click **Save**. After this, the Download Complete box will appear as shown below. From here you can choose to open the document to edit it, or Close the Download Complete box to edit the document later.

Step 3:

IT IS VERY IMPORTANT that after you've saved the file to your workstation and closed the Download Complete box that you click the **Complete Checkout** button in iRIS. This allows you to check the document (or upload the document) back into iRIS once you've finished editing it.

To cancel the Document Check - Out, click **Cancel**. Note: If you've already saved the file to your computer, the file will remain in your computer, however you will simply lose the option of checking the document back in.

A screenshot of the "Study Document Revision" form. The form has several fields: "Document Title" (External IRB approval), "Version Number" (1), "Version Date" (10/08/2019), and "Category" (External IRB Documents). Below these is a "Description" field. A status message says "This document is currently checked out by: Tiffany Andrews at 10/08/2019". There are two buttons: "Check-in Document..." and "Undo Check-out Document...". At the bottom right, there is a "Save Document" button with a floppy disk icon, which is highlighted with a red border.

8. If you are adding a new document for review, click "Add a new document". Then find the file by clicking "Choose file." After the file has been selected and uploaded, click "Save Document".

1.6 Please attach any documents that were approved by the IRB of record, along with the approval documentation:

A screenshot of the document attachment interface. It features three buttons: "Select or Revise Existing" (with a paperclip icon), "Add a New Document" (with a plus icon), and "Add Multiple Documents" (with a plus-in-a-circle icon). Below the buttons is a table with columns: "Detach", "Version", "Title", "Category", "Expiration Date", and "D". The table is currently empty, with the text "No Document(s) have been attached to this form." displayed below it.

Study Document Add: x

***Select the document to upload:** Choose File No file chosen

***Version Number:** 1 .0

Version Date: 09/18/2019

Category: --none--

Description:

Comments:

Save Document

9. When you are ready to submit the Deferral Update Form, click 'save and continue' until you reach the signoff page. If you are not the PI, there will be a 'notify the PI for signoff' button available.

Print Friendly
 Signoff and Submit

Section view of the Form | Entire view of the Form

Oregon State University
1.0 Human Research Protection Program ...

Form has been Completed!

Continue to Next Screen to Submit Your Form

Exit Form
 Signoff and Submit

10. The PI will click on 'approve', then 'save sign-off'. If the PI chooses to make additional edits, they can do that prior to signoff, however, if the signoff button seems to no longer be visible, they should go back to their 'Study Assistant' workspace, go to their tasks, and then click on the task called 'PI signoff' which will bring them back to the signoff page.

Save Signoff

Study Title: Test Application 06/19/2019---
Submission Reference Number: 002934

Include in PDF Packet	Submission Component Name
Submission Form(s):	
<input type="checkbox"/>	Deferral Update Form
Document(s)	
Category : External IRB Documents	
<input type="checkbox"/>	External IRB approval

Tiffany Andrews as Principal Investigator
do you Approve or Deny this submission?

Approve Deny

Comments:

Save Signoff